UNITED STATES DISTRICT COURT EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, STATE OF CALIFORNIA, STATE OF COLORADO, STATE OF CONNECTICUT, STATE OF DELAWARE, STATE OF FLORIDA. STATE OF GEORGIA. STATE OF HAWAII, STATE OF ILLINOIS, STATE OF INDIANA, STATE OF IOWA, STATE OF LOUISIANA, STATE OF MARYLAND, COMMONWEALTH OF MASSACHUSETTS, STATE OF MICHIGAN, STATE OF MINNESOTA, STATE OF MONTANA, STATE OF NEVADA, STATE OF NEW HAMPSHIRE, STATE OF NEW JERSEY, STATE OF NEW MEXICO, STATE OF NORTH CAROLINA, STATE OF OKLAHOMA, STATE OF RHODE ISLAND, STATE OF TENNESSEE, STATE OF TEXAS, COMMONWEALTH OF VIRGINIA, STATE OF WASHINGTON, ex rel. LENA STURGEON, ANTHONY FERRANTE, ANTHONY SCIOLE AND NATHAN NILES,

CIVIL ACTION NO.: 15-6829-CMR

v.

PHARMERICA CORP.,

PharMerica.

RULE 26(F) CONFERENCE DISCOVERY PLAN

Through their counsel, Relators Lena Sturgeon, Anthony Ferrante, Anthony Sciole, and Nathan Niles ("Relators") and PharMerica Corporation ("PharMerica" and together with Relators, the "Parties"), met and extensively conferred in accordance with Fed. R. Civ. P. 26(f) on multiple occasions. Through these efforts, the Parties stipulated to the "Confidentiality and HIPAA Qualified Protective Order" ("Protective Order"), "Stipulation Regarding the Collection and Production of Documents and Electronically Stored Information" ("ESI Protocol"), and Initial Case Scheduling Order, which were filed with the Court on November 8, 2019 (ECF No. 65) and entered by Orders dated November 12, 2019 (ECF Nos. 66-68). Pursuant to this

discussion, the Parties hereby submit the following discovery plan and proposed initial schedule for the Court's consideration.

I. PROCEDURAL HISTORY

On December 28, 2015, Relators initiated an action on behalf of the United States of America and various named States against PharMerica Corporation under the False Claims Act, 31 U.S.C. § 3729, et seq. ("FCA") and various State law corollaries. On May 31, 2019, Relators filed their Amended Complaint (ECF No. 43) alleging claims under §§ 3729(a)(1)(A) and 3729(a)(1)(B) of the FCA, as well as reverse FCA claims under § 3729(a)(1)(G). The Amended Complaint alleges that PharMerica altered and filled prescriptions without physician authorization in violation of state and federal law. In addition, Relator Sturgeon alleges an FCA retaliation claim under § 3730(h)(1) based upon the diminution of her authority, duties, and responsibilities at PharMerica after engaging in conduct protected by the FCA. The relevant period alleged in the Amended Complaint was from at least August 2013 through the present. Am. Compl. at ¶¶3, 101. PharMerica's Motion to Dismiss and Motion for Judicial Notice are fully briefed and are pending the Court's decision. The Court has not scheduled oral argument.

On November 8, 2019, the Parties filed a joint motion for entry of the ESI Protocol, Protective Order, and Initial Case Scheduling Order (ECF No. 65). The Court entered the stipulated agreements by Orders dated November 12, 2019 (ECF Nos. 66-68), setting the deadline for this discovery plan for December 6, 2019 and setting the case's Rule 16 pretrial conference for December 18, 2019 at 10:00 a.m.

On November 13, 2019, the Court requested a teleconference during which it questioned whether the federal and state governments should remain on the case caption when none of the listed governments had intervened in this Action. Counsel for the Parties maintained that the

governments, as the parties in interest, should remain on the caption. At the Court's request, on November 19, 2019, Assistant United States Attorney David A. Degnan submitted a letter to the Court urging the Court not to remove the government entities from the caption of the case, though noted Maryland does not object to being removed from the caption because the Maryland False Claims Act requires dismissal of *qui tam* claims if Maryland does not intervene.

II. THE RELEVANT TIME FRAME OF THIS ACTION

The parties have different views on the relevant statute of limitations and corresponding discovery period. Relators submit that the relevant statute of limitations is 10 years and the applicable discovery period is December 28, 2005. PharMerica submits that the 10 year statute of limitations does not apply and that the applicable discovery period is August 2013 through present. In an effort to resolve their dispute efficiently, the Parties have agreed to conduct some limited discovery into PharMerica's policies, procedures, and systems predating August 2013. If after conducting some limited discovery, the Parties are still unable to find a workable compromise, they will jointly submit the dispute over the applicable statute of limitations and corresponding relevant discovery period to the Court for its consideration.

III. SUBJECTS ON WHICH DISCOVERY MAY BE NEEDED

Relators anticipate seeking discovery on the following subjects, in addition to any others that may arise or become relevant as litigation progresses:

- PharMerica's policies, practices, procedures, controls and systems in place over prescription drug alterations, dispensations and billing;
- PharMerica's LTC400, Mpact, and MPSRX systems and any other relevant systems used to dispense and bill government health care programs for prescription drugs and all relevant data from those systems during the relevant time frame;
- PharMerica's receipt and retention of PointClickCare (PCC) data;
- PharMerica's compliance with the 2015 Corporate Integrity Agreement and Memorandum of Agreement with the Drug Enforcement Agency;

- PharMerica's contracts with drug wholesalers and manufacturers relating to pricing, rebates, discounts, and any other incentives offered to PharMerica for dispensing a particular drug, dose, and/or form and corresponding purchase history;
- PharMerica's contracts with government/third party payors regarding drugs, prices, rebates, discounts, and any other terms related to prescription drugs;
- All drug price lists and formularies PharMerica contends were applicable during the relevant time frame;
- Relevant data related to claims made by PharMerica on Medicare and Medicaid plans;
- PharMerica's creation of and any amendments to or maintenance of drug files maintained on the LTC400 during the relevant time frame; and
- PharMerica's prescription files.¹

PharMerica anticipates seeking discovery on the following subjects, in addition to any others that may arise or become relevant as litigation progresses:

- The policies and procedures of the Center for Medicare and Medicaid Services ("CMS") with respect to the payment of the fixed monthly amounts due to Medicare Part D Plan sponsors and with respect to the federal government's share of Medicaid payments to Managed Care Organizations and to Pharmacies insofar as they relate to the materiality of the alleged dispensing irregularities;
- The policies and procedures of the various state Medicaid programs with respect to the payment of the fixed monthly amounts due to Medicaid Managed Care Organizations and the fee for service amounts paid directly to pharmacies insofar as they relate to the materiality of the alleged dispensing irregularities;
- The policies and procedures of the various state Medicaid programs and Part D Plan sponsors with respect to their directive to pharmacies to dispense less expensive brand name drugs in place of an ordered drugs' more expensive generic counterpart;
- The positions of the various state Boards of Pharmacy on the authority of pharmacists to make the alleged prescription alterations;

pharmaceutical drug dispensed; and (9) dispensing technician and/or pharmacist.

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¹ "Prescriptions file" refers to the electronic and hard copy records relating to a particular medication dispensation containing without limitation the following information: (1) facility name, (2) prescribing physician's name, (3) patient's name, (4) manufacturer, brand, form, type, strength, quantity, and dose of the pharmaceutical drug being ordered, (5) date of the order, (6) date of the dispensation, (7) relevant government program Medicaid, Medicare Part A or Medicare Part D; (8) manufacturer, brand, form, type, strength quantity, and dose of the

- Relator Sturgeon's knowledge, or lack thereof, related to the functionality and design of the systems described in the Amended Complaint;
- Relator Sturgeon's knowledge, or lack thereof, related to proper dispensing practices in the long term care industry;
- The alleged increase in the cost per prescription that Reliant allegedly incurred after becoming a PharMerica customer;
- The circumstances of Relator Sturgeon's resignation from employment with PharMerica and the jury's determination in her prior litigation against PharMerica that PharMerica did not reduce or diminish her duties;
- The PCC systems in use during the relevant time period;
- The PCC data and any other prescription files used by Relator Sturgeon to conduct her audit of PharMerica's dispensing practices, relator Sturgeon's audit methodology, and the complete results of her audit;
- Reliant's policies, practices, procedures, controls and systems that governed medication administration and the prevention of medication errors;
- The findings of any state or federal surveys related to Reliant's medication administration and medication errors; and
- Reliant's calculation of its medication error rate and any efforts taken by Reliant to improve its medication error rate.

IV. TIMING, LIMITATIONS, AND FORM OF DISCOVERY

A. Initial Disclosures

The Parties have exchanged initial disclosures as required by Rule 26(a).

B. *Form of Discovery*.

Except as the Parties otherwise agree in writing, or except as the Court otherwise orders, all documents, data and other information produced in this litigation by Plaintiffs, Defendants, or any non-party shall be subject to the ESI Protocol and Protective Order.

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C. Document Production.

Absent other agreement of the Parties or Order of the Court for good cause shown, production of responsive documents shall be made on a rolling basis and completed as soon as practicable after responses are due.

D. <u>Sampling.</u>

It is Relators' position that a sampling protocol may be necessary with respect to prescription files. Relators suggest taking a randomized sample of claims for which the input PCC data and resulting dispense characteristics do not match. A number of courts have permitted the use of statistical sampling and extrapolation to prove liability and/or damages in FCA actions. See, e.g., United States v. Rogan, 517 F.3d 449, 453 (7th Cir. 2008) (rejecting the argument that each of the claims at issue had to be addressed and holding that "[s]tatistical analysis should suffice"); Waldmann v. Fulp, 259 F. Supp. 3d 579, 636 (S.D. Tex. 2016) (holding that expert's findings with respect to a sample of claims was sufficient to create fact issue defeating summary judgment); United States v. Robinson, 2015 WL 1479396, at *5-6 (E.D. Ky. Mar. 31, 2015) (same); United States v. AseraCare Inc., 2015 WL 8486874 (N.D. Ala. Dec. 4, 2014) (same); United States ex rel. Ruckh v. Genoa Healthcare, LLC, No. 8:11-CV-1303-T-23TBM, 2015 WL 1926417, at *3 (M.D. Fla. Apr.28, 2015) (expressing an inclination to allowing statistical sampling and extrapolation); United States ex rel. Martin v. Life Care Ctrs. of Am., Inc., Nos. 1:08-cv-251, 1:12-cv-64, 2014 U.S. Dist. LEXIS 142660, 2014 WL 4816006 (E.D. Tenn. Sept. 29, 2014) (same); United States v. Fadul, No. CIV.A.DKA 11-0385, 2013 WL 781614, at *2 (D. Md., Feb., 28, 2013) (finding the extrapolation method acceptable for Medicare and Medicaid claims); United States ex rel. Loughren v. UnumProvident Corp., 604 F.Supp.2d 259, 263 (D. Mass. 2009) (holding extrapolation is a reasonable method for

determining the number of false claims so long as the statistical methodology is appropriate); *United States ex rel. Doe v. DeGregorio*, 510 F.Supp.2d 877, 890 (M.D. Fla. 2007) (relying on an extrapolated overpayment figure derived from a prior audit when calculating remedies); *United States v. Cabrera–Diaz*, 106 F. Supp. 2d 234, 242 (D.P.R. 2000) (entering default judgment against defendants based on estimated overpayments revealed by a government audit).

PharMerica's position is that sampling cannot be used in FCA cases to determine liability. *United States v. Vista Hospice Care, Inc.*, No. 3:07-cv00604-M, 2016 WL 3449833, at *13 (N.D. Tex. Jun. 20, 2016); *United States ex rel. Michaels v. Agape Senior Cmty., Inc.*, No. 0:12–3466–JFA, 2015 WL 3903675, at *8 (D.S.C. June 25, 2015) (disallowing statistical sampling to prove liability or damages under the FCA and citing cases reflecting split of authority). Relators must prove their case on a prescription by prescription basis. *United States ex rel. Conroy v. Select Med. Corp.*, 307 F. Supp. 3d 896, 905 (S.D. Ind. 2018) (rejecting plaintiff's request to conduct discovery through nationwide sampling, in part, because "the plaintiffs have the burden to prove each false claim" and sampling would "upend the burden of proof in this case").

The Parties will continue to discuss this issue and work in good faith towards a resolution of these issues. Though the Parties will endeavor to find a compromise without intervention of the Court, any disputes over sampling that cannot be resolved by the parties will be jointly submitted to the Court.

E. <u>Depositions.</u>

The Parties agree that absent agreement of the Parties or for good cause shown, the Parties shall provide the noticing party with the witness's availability as soon as practicable, and the scheduling order should reflect that agreement. The Parties further agree to the following:

- *Number of Depositions*. Relators collectively may take no more than 20 fact depositions in this action, and Defendant may take no more than 20 fact depositions in this action without leave of the Court.
- Rule 30(b)(6) Depositions: Any Rule 30(b)(6) deposition shall count as one deposition, regardless of the number of topics, notices, or witnesses presented.

V. <u>CASE MANAGEMENT SCHEDULE.</u>

The Parties propose the following schedule:

Close of document discovery	15 months from entry of Scheduling Order
Deadline for fact depositions	6 months from close of document discovery
Exchange of affirmative expert reports, if any	3 months from deadline for fact depositions
Exchange of rebuttal expert reports, if any	60 days from exchange of affirmative expert reports
Close of expert discovery	45 days from exchange of rebuttal expert reports.
Summary judgment motions, if any	60 days from close of expert discovery
Oppositions to summary judgment motions	45 days from filing of summary judgment motions
Replies to opposition to summary judgment	30 days from filing of oppositions to summary judgment motions

V. PARTIES' POSITION ON ALTERNATIVE DISPUTE RESOLUTION.

Relators and PharMerica are amenable to mediation or other forms of alternative dispute resolution.

Respectfully submitted,

By its attorneys,

PHARMERICA CORPORATION,

/s/ Michael Manthei

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Dated: December 6, 2019

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on December 6, 2019, a true and correct copy of the foregoing document was electronically filed with the Clerk of the United States District Court of the Eastern District of Pennsylvania, which will therefore be served electronically upon all counsel of record via this Court's CM/ECF system.

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